

REMARKS

Applicant respectfully requests reconsideration. Claims 1, 2, 4-25 and 42 were previously pending in this application. Claims 1, 2, 4, 5, 9, 12, 13, 14, 15, 21, 23 and 24 have been amended. Support for these amendments is found throughout the specification and at least on page 4, lines 11-12 and lines 15-19, page 16, lines 13-14 and page 18, lines 17-23. New claims 86-98 have been added. Support for these claims is found throughout the specification and in pending claims 4, 5, 8-10 and 18-20. Support for claim 98 is found at least on page 18, lines 17-19. No new matter has been added.

As a result, claims 1, 2, 4-25, 42 and 86-98 are pending for examination with claims 1, 2, 21 and 86 being independent claims.

Withdrawn Objections, Rejections and Rejections Moot

Applicant acknowledges that the Examiner has withdrawn several previous objections and rejections as indicated in the Office Action on pages 2-4. Applicant further acknowledges that some rejections have been rendered moot due to the Amendment filed on March 19, 2007.

Objections

Claim 9 is objected to for the recitation "at least-10,000". Applicant has amended claim 9 to recite "at least 10,000 Daltons" as suggested by the Examiner to remove a typographical error. No new matter has been added.

Accordingly, withdrawal of the objection to claim 9 is respectfully requested.

Double Patenting Rejection

The Examiner provisionally rejected claims 1, 2, 6, 8, 9, 11, 14, 19 and 20 under the judicially created doctrine of obviousness-type double patenting over claim 63 of co-pending application 09/771,003. The Examiner also provisionally rejected claim 18 under the judicially created doctrine of obviousness-type double patenting over claim 67 of the co-pending application 09/771,003. According to the Examiner, the claims although not identical, are not patentably

distinct from each other because the product of claims 63 and 67 of the co-pending application falls within the scope of the recited claims.

Applicant respectfully disagrees and asserts that the claims are patentably distinct because the claimed compositions are different. The pending claims recite a composition comprising an isolated polysaccharide wherein less than 50% or less than 40% of all glucosamine amino groups are acetylated. The product of claim 63 of co-pending application 09/771,003 would not result in such a composition as evidenced by its disclosure. Throughout the disclosure of 09/771,003, the polysaccharide preparation is described as having at least 50% acetylation (see paragraphs 35 and 65) and in some instances in the range of 50-95% acetylation (see paragraph 67). The composition of claim 63 is therefore highly acetylated and does not fall within the scope of the pending claims which recite less than 50% acetylation or less than 40% acetylation.

There is also no motivation to make a composition having less than 50% or less than 40% acetylation given that co-pending application 09/771,003 teaches that highly acetylated polysaccharide is immunostimulatory (see page 3, lines 15-18 of the specification). One of ordinary skill in the art would have no apparent reason to make a polysaccharide preparation having less than 50% acetylation with the expectation that such a preparation would be immunostimulatory based on this disclosure, absent Applicant's present teachings. Therefore, the current claims are not rendered obvious and are patentably distinct from those currently claimed in co-pending application 09/771,003 (now Issued as U.S. Patent No. 7,252,828).

Accordingly, withdrawal of the rejection of claims 1, 2, 6, 8, 9, 11, 14, 19 and 20 is respectfully requested.

Rejections Under 35U.S.C. § 112, Second Paragraph

Claims 1, 2, 4-25 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has addressed each rejection in turn as outlined by the Examiner on pages 5-6 of the Office Action.

Claim 15 has been amended to recite "a carrier compound" for correct antecedent basis for claims 16 and 17. Support for this amendment is found at least on page 18, lines 7-23.

Claims 1 and 2 have been amended to remove the phrase “provided that less than 50% of the R groups are NH-CO-CH₃”.

Claim 2 has been amended to remove the phrase “having a length of at least two monomeric units”.

Concerning the Examiner’s rejection of claim 42, Applicant respectfully disagrees that there is improper antecedent basis in the limitation ‘the isolated polysaccharide of claim 1’. According to the MPEP § 706.03(d) “this form paragraph should ONLY be used in aggravated situations where the lack of antecedent basis makes the scope of the claim indeterminate”. This is not the present situation since claim 42 refers to the isolated polysaccharide which is clearly defined in claim 1 from which claim 42 depends. Further the MPEP states that “Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” MPEP § 2173.02. One of ordinary skill in the art would understand claim 42 to recite a pharmaceutical composition that comprises the isolated polysaccharide as defined in claim 1. Applicant therefore asserts that claim 42 is clear and definite.

Claim 23 has been amended to recite “the linker joined to the carrier compound”. Claim 23 has also been amended to depend from claim 21.

Claim 24 has been amended to recite “one of said Y1, Y2 or Y3”.

Claim 21 has been rewritten as an independent claim.

Claim 14 has been amended to recite “is at least 90% pure, at least 95% pure, at least 97% pure, or at least 99% pure” as suggested by the Examiner. Support for this amendment is found at least on page 16, lines 13-14.

Claims 1 and 3 have been amended to recite “has” in place of “having” as suggested by the Examiner.

The claims are considered clear and definite.

Accordingly, withdrawal of the rejection of claims 1, 2, 4-25 and 42 under 35 U.S.C. § 112, second paragraph for indefiniteness is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 2, 4-16, 18-24 and 42 are rejected under 35 U.S.C. § 102(b) as being anticipated by McKenney *et al.* as evidenced by Joyce *et al.*, McKenney *et al.* (2000) and Maira-Litrán *et al.* According to the Examiner, the PS/A composition disclosed in McKenney *et al.* is the same PS/A compound presently claimed.

Applicant respectfully disagrees in part. The PS/A preparation disclosed in McKenney *et al.* (1998) does not anticipate the claimed composition comprising an isolated polysaccharide having less than 50% or less than 40% of glucosamine amino groups substituted with acetate because it is not the same composition. The PS/A preparation disclosed in McKenney *et al.* (1998) was mistakenly identified as having a high quantity of succinate (65-100%) and a low quantity of acetate (less than 50% the level of succinate if present at all) (see page 4714, left column, second paragraph). McKenney *et al.* (2000), provides a further analysis of the PS/A preparation disclosed in McKenney *et al.* (1998) but provides no further reference to the level of acetylation of this earlier preparation other than to reiterate that the product is a polymer of β -1-6 linked glucosamine residues primarily substituted with succinate with some acetate (see page 39, right column, first full paragraph).

Maira-Litrán *et al.* teaches that the PS/A preparation disclosed in McKenney *et al.* (1998) and mistakenly identified as poly-N-succinyl glucosamine is actually PNAG, a high-molecular weight, highly acetylated (95 to 100% N-acetylation) polymer of β -1-6-linked glucosamine residues.

Joyce *et al.* confirm that the PS/A preparation disclosed in McKenney *et al.* (1998) was misidentified as an N-succinylated product (see page 904, left column, last paragraph), but provided no further analysis of the PS/A preparation disclosed in McKenney *et al.* (1998). Rather, Joyce *et al.* disclosed a polysaccharide preparation produced by *S. aureus* MN8m strain comprising a polymer of β -1-6 linked glucosamine residues and having 45-60% N-acetyl (see abstract). There is no indication however in the disclosure of Joyce *et al.* that this polysaccharide preparation is the same PS/A preparation that was misidentified in McKenney *et al.* (1998) (i.e., there is no representation by Joyce *et al.* that the preparation of McKenney *et al.* (1998) was actually 45-60%

acetylated or that Joyce *et al.* used the same procedure as McKenney *et al.* (1998) to make its 45-60% acetylated preparation).

Therefore, the PS/A preparation disclosed in McKenney *et al.* (1998) is a highly acetylated polyglucosamine having at least 95% acetylation. The PS/A preparations disclosed in McKenney *et al.* (1998) and Maira-Litrán *et al.* do not anticipate the claimed compositions having less than 50% or less than 40% glucosamine amino groups substituted with acetate. Joyce *et al.* and McKenney *et al.* (2000) do not change this outcome.

Accordingly, withdrawal of the rejection of claims 1, 2, 4-16, 18-24 and 42 under 35 U.S.C. § 102(b) is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 17 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McKenney *et al.* as applied to claims 1, 15, 22 and 21 above, and further in view of Pier *et al.* (Published application no. 20020119166). According to the Examiner, it would have been obvious to one of ordinary skill in the art to conjugate the isolated β -1,6-glucosamine polysaccharide of McKenney *et al.* to an art-known carrier using an art-known conjugation technique as taught by Pier *et al.*

Applicant respectfully disagrees in part. The combination of the PS/A preparation of McKenney *et al.* with the conjugation technique of Pier *et al.* does not produce the claimed compositions having less than 50% or less than 40% glucosamine amino groups substituted with acetate. As discussed above, the polysaccharide preparation disclosed in McKenney *et al.* is highly acetylated (95 to 100% N-acetylation). The combination of the highly acetylated polysaccharide preparation disclosed in McKenney *et al.* with the conjugation technique of Pier *et al.* would produce a highly acetylated β -1,6-glucosamine polysaccharide conjugated to a carrier protein or peptide. The claims recite a composition having less than 50% or less than 40% glucosamine amino groups substituted with acetate. There is no motivation or apparent reason to make a composition having less than 50% or less than 40% glucosamine amino groups substituted with acetate in the

teachings of McKenney *et al.* in view of Pier *et al.* Therefore, this combination does not render the claims obvious.

Accordingly, withdrawal of the rejection of claims 17 and 25 under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

Applicant respectfully requests reconsideration. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

The Director is hereby authorized to charge \$1100.00 to cover the three month extension of time fee and the extra claim fee as well as any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No. B0801.70255US01.

Dated: November 15, 2007

Respectfully submitted,

By Marie Aucoin

Marie A. Aucoin, Ph.D.

Registration No.: 59,414

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000

x11/15/07x